REMARKS

Claims 1-39 are pending in this application upon entry of this amendment. Claims 1-8 and 39 are currently under examination on the merits. Claim 1 has been amended to more clearly recite the claimed invention. Support for the amendments can be found in the application as filed, for example, at paragraph [0104]. Claims 9-38 have been withdrawn. Applicants reserve the right to file one or more continuation, divisional, or continuation-in-part applications to any withdrawn subject matter. No new matter has been added.

I. The Rejections Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

Claims 1-8 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action alleges that one skilled in the art would not conclude that the instant specification provided adequate support for a method comprising administration of compounds of Formula I where X is C_2-C_5 alkenyl or C_2-C_5 alkynyl as recited in the instant claims.

Applicants respectfully traverse the rejection. Applicants direct the Examiner's attention to section 5.2.1 COMPOUNDS OF FORMULA I. Specifically, paragraph [0169] discloses "[i]n one embodiment, X is C_2-C_5 alkenyl;" and paragraph [0170] discloses "[i]n one embodiment, X is C_2-C_5 alkynyl."

Accordingly, the specification as filed does in fact provide written description support for the claims. Therefore, Applicants respectfully request that this rejection of claims 1-8 and 39 under 35 U.S.C. § 112, first paragraph, be withdrawn.

II. The Rejection under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 1-8 and 39 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,962,437 to Kucera *et al.* ("Kucera I") in view of U.S. patent No. 5,770,584 to Kucera *et al.* ("Kucera II").

The Office Action alleges that the instantly claimed methods of treating RSV infections comprising administering a compound of Formula I would have been *prima facia* obvious to one

of ordinary skill in the art at the time the invention was made. According to the office action, Kucera I clearly motivate one skilled in the art to use compounds of Formula I to treat viral infections and even teach that respiratory syncytial virus infections are a type of infection that may be treated with the compounds of the invention. The office action further states that Kucera II is provided as evidence that compounds having lower alkyl groups in the R2 position maintain antiviral activity. The office action then concludes that one skilled in the art would have been imbued with at least

Applicants remind the Examiner that when the prior art genus is so large that it does not suggest the claimed species or sub-genus, it has been held that a case of *prima facie* obviousness is not made out even though the species or sub-genus is a member of the described prior art genus. Two cases illustrate this point: *In re Jones* and *In re Baird*.

In *In re Jones*, the claim at issue was to a specific salt of a known herbicide, dicamba. *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992). The PTO had found the claimed salt *prima facie* obvious over a prior art reference that, although it did not disclose the specifically claimed salt, disclosed salts of dicamba, including "a genus which admittedly encompasses the claimed salt." *Id.* at 349. The Federal Circuit reversed, holding that the claimed salt was not sufficiently similar in structure to any of the specifically disclosed salts of the prior art reference to create a *prima facie* case of obviousness and that "[t]he lack of close similarity of structure is not negated by the fact that the claimed salt is a member of [the prior art reference's] broadly disclosed genus of substituted ammonium salts of dicamba." *Id.* at 350. The Federal Circuit rejected the proposition that "regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it." *Id.* Indeed, in *Jones*, the prior art genus disclosed a "potentially infinite genus of 'substituted ammonium salts' of dicamba," without describing or suggesting the specifically claimed salt.

Therefore, without more, the fact that a claimed compound falls within the scope of a large prior art genus may not render the claimed compound *prima facie* obvious. In addition, as discussed above, absent a finding of *prima facie* obviousness, the burden does not shift to the patent applicant to come forward with evidence of non-obviousness.

In re Baird involved a claim to toner composition comprising a bisphenol A. *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994). The PTO rejected the claimed composition over a prior art reference that disclosed a broad genus of compounds that included the claimed bisphenol A compound. The Federal Circuit reversed. The prior art genus encompassed more than "100 million different diphenols." *Id.* at 382. "While the [prior art] formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of [the prior art reference] suggesting that one should select such variables." *Id.* Indeed, the Federal Circuit found that the prior art reference actually "appears to teach away" from the claimed compound because the prior art reference focused on structurally different and more complex subclasses of compounds within the genus. *Id.* The Federal Circuit summed up by stating that "[a] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds." *Id.*

As illustrated on page 5 of the office action, Kucera discloses compounds of formula I, wherein

> In the compounds of Formula I, R_1 is a branched or unbranched, saturated or unsaturated C_6 to C_{18} alkyl group optionally substituted from 1 to 5 times with --OH, --COOH, oxo, amine, or substituted or unsubstituted aromatic; X is selected from the group consisting of NHCO, CH_3 NCO, CONH, $CONCH_3$, S, SO, SO_2, O, NH, and NCH_3; R_2 is a branched or unbranched, saturated or unsaturated C_6 to C_{14} alkyl group optionally substituted from 1 to 5 times with --OH, --COOH, oxo, amine, or substituted or unsubstituted aromatic; Y is selected from the group consisting of NHCO, CH_3, NCO, CONH, $CONCH_3$, S, SO, SO_2, O, NH, and NCH_3 ; R_6 is a branched or unbranched C_2 to C_6 alkyl group; and R_3, R_4, and R_5 are independently methyl or ethyl, or R_3 and R_4 together form an aliphatic or heterocyclic ring having five or six members and R_5 is methyl or ethyl.

(*See* Kucera I at col. 2, lines 13-30).

Thus, similar to *Baird*, the genus of formula I disclosed in Kucera I encompass millions of compounds. The Office Action alleges that Kucera I discloses treating RSV with the compounds of the invention and further that Kucera motivates those skilled in the art to use the

compounds disclosed by Kucera I to treat various types of virus. However, Kucera does not disclose or suggest the compounds of the claimed invention, as amended, nor provide suggestion or motivation to utilize shorter branched alkyl, alkenyl or alkynyl groups. Indeed, Kucera is silent with regard to compounds where R_2 is an O coupled to a C_1-C_5 alkyl, C_2-C_5 alkenyl, or C_2-C_5 alkynyl. The fact that Kucera discloses the R_2 group as a C_6-C_{18} alkyl group would not motivate one of ordinary skill in the art to include a C_1-C_5 alkyl group as recited by the instant claims. The Examiner alleges that Kucera II is provided as evidence that compounds having lower alkyl groups in the R_2 position maintain antiviral activity. The Examiner points to Example 6 in Kucera II to allege the suggestion to modify the R_2 position to include lower alkyl groups. However, Kucera II is directed to the treatment of hepatitis virus infections and not generally to infections. Thus, there would be no motivation to combine the Kucera I and Kucera II references.

Even assuming there was a motivation to combine the references, Applicants further submit that the currently claims, as amended, are directed to methods for treating a host infected with respiratory syncytial virus (RSV) comprising administering to a host in need thereof an anti-RSV effective amount of a compound of Formula I:

or a pharmaceutically acceptable salt thereof,

wherein: R_1 is selected from the group consisting of -NHC(O)Y, where Y is C_1-C_{22} alkyl, C_2-C_{22} alkenyl, and C_2-C_{22} alkynyl; R_2 is selected from the group consisting of -OX, where X is C_1-C_5 alkyl, C_2-C_5 alkenyl, and C_2-C_5 alkynyl; and R_3 is phosphocholine.

Applicants submit that the claims have been amended to recite the language "in need thereof." The subject matter recited in the pending claims is not obvious, based upon the cited references, because the Office has failed to show that there was an intent to use the compositions

for treating a host in need thereof infected with respiratory syncytial virus (RSV). When a claim recites a method of treating a disorder to be performed on a patient 'in need of' such treatment, the proper construction of the claim is that the method be practiced in order to treat that specific disorder. *Jansen v. Rexall Sundown*, 342 F.3d 1329, 1333-34, 68 U.S.P.Q.2d 1154, 1157-58 (Fed. Cir. 2003); *Rapoport v. Dement*, 254 F.3d 1053, 1060-61 (Fed. Cit. 2001). In *Rapoport v. Dement*, the claim under dispute recited:

> A method of treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . .

254 F.3d at 1060. The court reasoned that the phrase "to a patient in need of such treatment" in the body of the claim would not have a proper antecedent basis without treating the claim preamble as claim feature. *Id.* at 1059. The court further explained that this claim feature required that the azapirone compound be administered in order to treat sleep apneas. *Id.* at 1060-61 (analyzing whether an allegedly anticipatory reference disclosed administration of an azapirone compound with intent to cure sleep apneas and stating that the reasons for administering the compound were relevant to an anticipation analysis). A subsequent Federal Circuit decision confirmed the conclusion of the *Rapoport* court. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (confirming that the Rapoport method of treatment claim required that the method be practiced in order to treat sleep apneas). Thus, although the present rejection is an obviousness rejection and not an anticipation rejection, the claim must still be construed accordingly.

In *Jansen*, a similar method of treatment claim was interpreted to require that a drug combination be administered in order to treat the specified disorder. *Id.* In *Jansen*, the claim under dispute recited:

> 1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B12 and at least about 0.5 mg. of folic acid.

Id. at 1330, 68 U.S.P.Q.2d at 1155. Relying in part on the *Rapoport* decision, the court interpreted the claim preamble as a statement of the "intentional purpose for which the method must be performed," rather than "a statement of effect that may or may not be desired or appreciated," thus rendering the preamble as an element of the claim. *Id.* at 1333, 68 U.S.P.Q.2d at 1158. That the specific type of anemia and the "in need" language was added to the claim during prosecution to achieve allowance of the claim bolstered the court's conclusion that the two phrases should be read together and considered an element of the claim. *Id.* at 1334, 68 U.S.P.Q.2d at 1158. As stated by the court:

> . . .that "need" must he recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances or their addition suggest they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megoblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention.

Id. at 1334, 68 U.S.P.Q.2d at 1158. Accordingly, a method claim further reciting "in need thereof" language should be properly construed such that the method is practiced with intent to reduce the particular disorder or symptom recited in the claim.

Here, as in *Jansen* and *Rapoport*, the pending claims recite that the methods are used on animals "in need thereof." There is nothing in the references that discloses an intent to treat a host infected with respiratory syncytial virus (RSV) comprising administering to a host in need thereof of a composition including a compound of formula I.

Accordingly, Kucera I in view of Kucera II does not render the claimed invention obvious. Therefore, Applicants respectfully request that the rejection of claims 1-8 and 39 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

III. Conclusions

It is respectfully submitted that the rejections to the claims have been overcome. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the

undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issues payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

Respectfully submitted,
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